K111413

MÖLNLYCKE HEALTH CARE

JAN 3 0 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Biogel® PI Indicator® Underglove

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared:	August 25, 2011
Applicant:	Mölnlycke Health Care US, LLC 5550 Peachtree Parkway, Suite 500 Norcross, GA 30092 Registration number: 3004763499 Owner/Operator Number: 9067000
Official Correspondent:	Angela L. Bunn, RAC Director, Regulatory Affairs for the Americas Tel: 678-250-7930 Fax: 678-245-7746 e-mail: angela.bunn@molnlycke.com
Trade/Proprietary Name:	Biogel® PI Indicator® Underglove
Common Name:	Surgeon's Glove
Classification Name:	Surgeon's Glove
Device Class:	Class I
Regulation Number:	21 CFR 878.4460
Product Code:	KGO
Predicate Device Name(s):	Biogel® PI Indicator® Underglove (K081180 – originally cleared under Skinsense Polyisoprene Underglove)

Description of Device:

The proposed device, the Biogel® PI Indicator® Underglove is manufactured of polyisoprene colored with blue pigmentation. The Biogel® PI Indicator® Underglove is manufactured of the exact same material and coated with the Biogel® Coating which is used on the currently cleared device that has been legally marketed by Mölnlycke Health Care for many years with the addition of a surfactant.

Intended Use/Indication for Use:

The Biogel® PI Indicator® Underglove is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

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Technological Characteristics:

The Biogel® PI Indicator® Underglove is substantially equivalent to the Biogel® PI Indicator® Underglove (K081180 – originally cleared under Skinsense Polyisoprene Underglove). The assessed devices have the same indications for use, materials, product design, labeling claims and method of operation.

The only difference in the proposed device, Biogel® PI Indicator® Underglove is the addition of a surfactant.

The Biogel® PI Indicator® Underglove characteristics are summarized below as compared to ASTM requirements.

Characteristic	Standard
Dimensions	Meets ASTM D3577
Physical Properties	Meets ASTM D3577
Freedom from Holes	Meets ASTM D3577
Biocompatibility	Meets ISO 10993-1
LAL Test Results	ASTM D7102

Performance Data:

The performance data are summarized above.

Clinical Testing:

No clinical data was required.

Conclusion:

Based on the performance testing, it can be concluded that the Biogel® PI Indicator® Underglove is equivalent to the Biogel® PI Indicator® Underglove (K081180 – originally cleared under Skinsense Polyisoprene Underglove) predicate with respect to intended use, materials, design, and technological characteristics.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Angela L. Bunn, RAC
Director, Regulatory Affairs for the Americas
Molnlycke Health Care, US LLC
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

JAN 30 2012

Re: K111413
Trade/Device Name: Biogel® PI Indicator® Underglove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: January 13, 2012
Received: January 17, 2012

Dear Ms. Bunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MÖLNLYCKE HEALTH CARE

INDICATIONS FOR USE

510(k) Number (if known): K111413

Device Name: **Biogel® PI Indicator® Underglove**

Indications For Use:

The Biogel® PI Indicator® Underglove is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth A. Claus-Williams
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111413

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